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Santé Canada

Pest Management
Regulatory Agency

Agence de réglementation
de la lutte antiparasitaire

Regulatory Directive

DIR2007-01

First Aid Labelling Statements

This Regulatory Directive outlines Health Canada's Pest Management Regulatory Agency (PMRA) required modifications to label statements addressing first aid measures in the event of accidental ingestion of pesticides.

The intent of this initiative is to reflect modern medical practices in relation to handling poisoning incidents and further harmonize pesticide labelling practices with the United States.

(publié aussi en français)

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1.0 Purpose

The purpose of this document is to communicate to industry and other interested parties, revisions to label statements addressing first aid measures in the event of accidental ingestion of pesticides. The intent is to reflect modern medical practices in relation to handling poisoning incidents and further harmonize pesticide labelling practices with the United States. These changes involve the FIRST AID section of the label.

These revisions replace the corresponding requirements, where applicable, as detailed in Regulatory Proposal PRO2006-02, *First Aid Labelling Statements*, and the *Registration Handbook*.

2.0 Background

The Pest Control Products Regulations require that pesticide product labels include first aid instructions, specifically "the practical measures to be taken in the event of poisoning, intoxication or injury caused by the control product". The PMRA procedural practice indicates these measures are those that can be safely implemented prior to obtaining medical assistance. Information directed toward medical professionals appears on a product label under a separate section entitled TOXICOLOGICAL INFORMATION. If medical attention is recommended under the FIRST AID section, the following statement is required to be added to the section: "Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention".

First aid statements provide vital information to pesticide users, physicians and emergency response personnel; therefore, the PMRA expects pesticide labels to reflect modern medical procedures and treatment. The American Academy of Pediatrics (AAP) issued a policy statement (November 2003) regarding the use of syrup of ipecac, an emetic agent, in the treatment of a poisoning incident in a child. Their policy was revised based on research that failed to show benefit for children who were treated with ipecac following an ingestion event. Consequently, the AAP recommends that syrup of ipecac should no longer be used routinely as a poison treatment intervention at home. Labels for some pesticide products still recommend the use of syrup of ipecac under the FIRST AID instructions when the product has been ingested.

Furthermore, the PMRA is aware that the induction of vomiting as a first aid measure has fallen into disfavour by the medical community due to the complications that can arise from the aspiration of vomitus. Labels for many pesticide products still recommend the induction of vomiting under the FIRST AID instructions when the product has been ingested (an exception where induction of vomiting has been contraindicated is for products containing more than or equal to 10% petroleum distillates).

In re-examining the appropriateness of existing first aid statements, the PMRA also examined current practices of pesticide labelling within the United States Environmental Protection Agency (USEPA). The USEPA issued a Pesticide Registration (PR) Notice (PR Notice 2001-1) in January 2001 providing guidance on the content of first aid statements. The PMRA reviewed the PR Notice to determine potential areas of harmonization in label language, which are also reflected in this directive.

3.0 Consultation

The PMRA consulted with the medical community on first aid statements late in 2003, and early in 2004. Specifically, the Canadian Pediatric Society (CPS) and the Canadian Medical Association (CMA) were asked for their views regarding the deletion of syrup of ipecac as well as the deletion of induction of vomiting as a first aid remedial measure. The CPS and CMA were also asked if they were aware of any potential exceptions to the proposed deletions. Lastly, the CPS and CMA were consulted on proposed wording regarding first aid for the ingestion of a pesticide.

The CPS endorsed the recommendation to delete syrup of ipecac as a first aid treatment for the ingestion of a pesticide, indicating the home use of ipecac had never been one of their policy recommendations. The CMA noted the AAP's observations that there is insufficient evidence of the efficacy of ipecac and that ipecac has been improperly administered at home and abused by people with eating disorders. The CMA also endorsed the recommendation to delete syrup of ipecac as a first aid remedial measure. Neither the CPS nor the CMA noted any exceptions to their recommendations.

The CPS as well as the CMA endorsed the deletion of induction of vomiting as a first aid remedial measure with no exceptions.

The following first aid statement is used on pesticide labels in the United States for those products that warrant such statements (i.e., triggered by the toxicology).

IF SWALLOWED

Call a poison control centre or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give anything by mouth to an unconscious person.

The CPS as well as the CMA agreed with the proposed wording of the above statement. Further, the CPS suggested the addition of a statement regarding dermal exposure. Although not the subject of this regulatory directive, statements regarding first aid measures for all routes of exposure are required when triggered by the hazard information for a particular product (Appendix I).

The USEPA determined that having a person sip or drink water or milk after ingesting a product containing petroleum distillates is unwarranted. Although the Canadian medical community was not consulted on this point, it should be noted that the USEPA made this determination after discussion with their medical experts. Thus, the standard first aid statement for products containing **any level** of petroleum distillates is as follows:

IF SWALLOWED

Call a poison control centre or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give **any** liquid to the person. Do not give anything by mouth to an unconscious person.

4.0 Summary

On the basis of the advice provided by the medical community, the PMRA recommends the following.

- Any reference to syrup of ipecac as a first aid remedial measure must be deleted from all pesticide labels.
- Any reference to induction of vomiting as a first aid remedial measure must be deleted from all pesticide labels.
- When first aid statements are triggered for the oral route of ingestion by the hazard information, the following text should be used for products **without** petroleum distillates:

IF SWALLOWED

Call a poison control centre or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give anything by mouth to an unconscious person.

- When first aid statements are triggered for the oral route of ingestion by the hazard information, the following text should be used for products **with** any level of petroleum distillates:

IF SWALLOWED

Call a poison control centre or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give **any** liquid to the person. Do not give anything by mouth to an unconscious person.

While this directive provides guidance on generic first aid statements applicable to most products, these statements may not always be medically appropriate for a particular pesticide product. There may be products for which unique acute toxic effects are identified that necessitate additions or changes to the generic first aid statements. It is the responsibility of the registrant to identify these products to the PMRA along with the rationale for modifying the proposed generic first aid statements.

5.0 Scope

This policy applies to the FIRST AID section of any label for all products subject to registration under the *Pest Control Products Act*.

6.0 Policy

The PMRA proposes to implement these label changes using the most efficient means. It is proposed that these label statements would become effective within 60 days of this regulatory directive for any new applications or applications for amendment. For new applications or applications for amendment that are with the PMRA for which the Agency has not yet issued an annotated label, the PMRA will incorporate the appropriate changes into the label. For products that are already registered and do not have a current open application, amendments should be made at renewal.

Appendix I Guidance for Content of First Aid Instructions¹

If swallowed (no petroleum distillates in formulation)	Call a poison control centre or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give anything by mouth to an unconscious person.
If swallowed (petroleum distillates in formulation)	Call a poison control centre or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.
If on skin or clothing	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15–20 minutes. Call a poison control centre or doctor for treatment advice.
If inhaled	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control centre or doctor for further treatment advice.
If in eyes	Hold eye open and rinse slowly and gently with water for 15–20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control centre or doctor for treatment advice.
	If medical attention is required under the FIRST AID section, the following statement should be added to the section: Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention.

¹ These statements are to be used when triggered by the hazard information for the product. Registrants may opt to use statements when no hazard trigger is identified.

² These statements should be used unless medically incorrect for the product.

